

# STATE OF NEW YORK

8147

## IN SENATE

January 26, 2022

Introduced by Sen. PERSAUD -- read twice and ordered printed, and when printed to be committed to the Committee on Insurance

AN ACT to amend the insurance law and the social services law, in relation to requiring health insurance policies and medicaid to cover biomarker testing for certain purposes

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Subsection (i) of section 3216 of the insurance law is  
2 amended by adding a new paragraph 11-b to read as follows:

3 (11-b) (A) Every policy which provides medical, major medical, or  
4 similar comprehensive-type coverage shall provide coverage for biomarker  
5 testing for the purposes of diagnosis, treatment, appropriate manage-  
6 ment, or ongoing monitoring of a covered person's disease or condition  
7 when the test is supported by medical and scientific evidence, includ-  
8 ing, but not limited to:

9 (i) labeled indications for a test approved or cleared by the food and  
10 drug administration of the United States government or indicated tests  
11 for a food and drug administration approved drug;

12 (ii) centers for medicare and medicaid services national coverage  
13 determinations and medicare administrative contractor local coverage  
14 determinations; or

15 (iii) nationally recognized clinical practice guidelines and consensus  
16 statements.

17 (B) Such coverage shall be provided in a manner that shall limit  
18 disruptions in care including the need for multiple biopsies or biospe-  
19 cimen samples.

20 (C) The covered person and prescribing practitioner shall have access  
21 to a clear, readily accessible, and convenient process to request an  
22 exception to a coverage policy provided pursuant to the provisions of  
23 this paragraph. Such process shall be made readily accessible on the  
24 website of the insurer.

25 (D) As used in this paragraph, the following terms shall have the  
26 following meanings:

EXPLANATION--Matter in italics (underscored) is new; matter in brackets  
[-] is old law to be omitted.

LBD13311-02-2

1 (i) "Biomarker" means a characteristic that is objectively measured  
2 and evaluated as an indicator of normal biological processes, pathogenic  
3 processes, or pharmacologic responses to a specific therapeutic inter-  
4 vention. Biomarkers include but are not limited to gene mutations or  
5 protein expression.

6 (ii) "Biomarker testing" means the analysis of a patient's tissue,  
7 blood, or other biospecimen for the presence of a biomarker. Biomarker  
8 testing includes but is not limited to single-analyte tests, multi-plex  
9 panel tests, and whole genome sequencing.

10 (iii) "Consensus statements" means statements developed by an inde-  
11 pendent, multidisciplinary panel of experts utilizing a transparent  
12 methodology and reporting structure and with a conflict of interest  
13 policy. Such statements are aimed at specific clinical circumstances and  
14 base the statements on the best available evidence for the purpose of  
15 optimizing the outcomes of clinical care.

16 (iv) "Nationally recognized clinical practice guidelines" means  
17 evidence-based clinical practice guidelines developed by independent  
18 organizations or medical professional societies utilizing a transparent  
19 methodology and reporting structure and with a conflict of interest  
20 policy. Clinical practice guidelines establish standards of care  
21 informed by a systematic review of evidence and an assessment of the  
22 benefits and costs of alternative care options and include recommenda-  
23 tions intended to optimize patient care.

24 § 2. Subsection (1) of section 3221 of the insurance law is amended by  
25 adding a new paragraph 11-b to read as follows:

26 (11-b) (A) Every insurer delivering a group or blanket policy or issu-  
27 ing a group or blanket policy for delivery in this state that provides  
28 coverage for medical, major medical, or similar comprehensive-type  
29 coverage shall provide coverage for biomarker testing for the purposes  
30 of diagnosis, treatment, appropriate management, or ongoing monitoring  
31 of a covered person's disease or condition when the test is supported by  
32 medical and scientific evidence, including, but not limited to:

33 (i) labeled indications for a test approved or cleared by the food and  
34 drug administration of the United States government or indicated tests  
35 for a food and drug administration approved drug;

36 (ii) centers for medicare and medicaid services national coverage  
37 determinations and medicare administrative contractor local coverage  
38 determinations; or

39 (iii) nationally recognized clinical practice guidelines and consensus  
40 statements.

41 (B) Such coverage shall be provided in a manner that shall limit  
42 disruptions in care including the need for multiple biopsies or biospe-  
43 cimen samples.

44 (C) The covered person and prescribing practitioner shall have access  
45 to a clear, readily accessible, and convenient process to request an  
46 exception to a coverage policy provided pursuant to the provisions of  
47 this paragraph. Such process shall be made readily accessible on the  
48 website of the insurer.

49 (D) As used in this paragraph, the following terms shall have the  
50 following meanings:

51 (i) "Biomarker" means a characteristic that is objectively measured  
52 and evaluated as an indicator of normal biological processes, pathogenic  
53 processes, or pharmacologic responses to a specific therapeutic inter-  
54 vention. Biomarkers include but are not limited to gene mutations or  
55 protein expression.

1 (ii) "Biomarker testing" means the analysis of a patient's tissue,  
2 blood, or other biospecimen for the presence of a biomarker. Biomarker  
3 testing includes but is not limited to single-analyte tests, multi-plex  
4 panel tests, and whole genome sequencing.

5 (iii) "Consensus statements" means statements developed by an inde-  
6 pendent, multidisciplinary panel of experts utilizing a transparent  
7 methodology and reporting structure and with a conflict of interest  
8 policy. Such statements are aimed at specific clinical circumstances and  
9 base the statements on the best available evidence for the purpose of  
10 optimizing the outcomes of clinical care.

11 (iv) "Nationally recognized clinical practice guidelines" means  
12 evidence-based clinical practice guidelines developed by independent  
13 organizations or medical professional societies utilizing a transparent  
14 methodology and reporting structure and with a conflict of interest  
15 policy. Clinical practice guidelines establish standards of care  
16 informed by a systematic review of evidence and an assessment of the  
17 benefits and costs of alternative care options and include recommenda-  
18 tions intended to optimize patient care.

19 § 3. Section 4303 of the insurance law is amended by adding a new  
20 subsection (p-1) to read as follows:

21 (p-1) (1) A medical expense indemnity corporation, a hospital service  
22 corporation or a health service corporation that provides coverage for  
23 medical, major medical, or similar comprehensive-type coverage shall  
24 provide coverage for biomarker testing for the purposes of diagnosis,  
25 treatment, appropriate management, or ongoing monitoring of a covered  
26 person's disease or condition when the test is supported by medical and  
27 scientific evidence, including, but not limited to:

28 (A) labeled indications for a test approved or cleared by the food and  
29 drug administration of the United States government or indicated tests  
30 for a food and drug administration approved drug;

31 (B) centers for medicare and medicaid services national coverage  
32 determinations and medicare administrative contractor local coverage  
33 determinations; or

34 (C) nationally recognized clinical practice guidelines and consensus  
35 statements.

36 (2) Such coverage shall be provided in a manner that shall limit  
37 disruptions in care including the need for multiple biopsies or biospe-  
38 cimen samples.

39 (3) The covered person and prescribing practitioner shall have access  
40 to a clear, readily accessible, and convenient process to request an  
41 exception to a coverage policy provided pursuant to the provisions of  
42 this subsection. Such process shall be made readily accessible on the  
43 website of the insurer.

44 (4) As used in this subsection, the following terms shall have the  
45 following meanings:

46 (A) "Biomarker" means a characteristic that is objectively measured  
47 and evaluated as an indicator of normal biological processes, pathogenic  
48 processes, or pharmacologic responses to a specific therapeutic inter-  
49 vention. Biomarkers include but are not limited to gene mutations or  
50 protein expression.

51 (B) "Biomarker testing" means the analysis of a patient's tissue,  
52 blood, or other biospecimen for the presence of a biomarker. Biomarker  
53 testing includes but is not limited to single-analyte tests, multi-plex  
54 panel tests, and whole genome sequencing.

55 (C) "Consensus statements" means statements developed by an independ-  
56 ent, multidisciplinary panel of experts utilizing a transparent method-

1 ology and reporting structure and with a conflict of interest policy.  
2 Such statements are aimed at specific clinical circumstances and base  
3 the statements on the best available evidence for the purpose of opti-  
4 mizing the outcomes of clinical care.

5 (D) "Nationally recognized clinical practice guidelines" means  
6 evidence-based clinical practice guidelines developed by independent  
7 organizations or medical professional societies utilizing a transparent  
8 methodology and reporting structure and with a conflict of interest  
9 policy. Clinical practice guidelines establish standards of care  
10 informed by a systematic review of evidence and an assessment of the  
11 benefits and costs of alternative care options and include recommenda-  
12 tions intended to optimize patient care.

13 § 4. Subdivision 2 of section 365-a of the social services law is  
14 amended by adding a new paragraph (jj) to read as follows:

15 (jj) (i) biomarker testing for the purposes of diagnosis, treatment,  
16 appropriate management, or ongoing monitoring of a recipient's disease  
17 or condition when the test is supported by medical and scientific  
18 evidence, including, but not limited to:

19 (1) labeled indications for a test approved or cleared by the food and  
20 drug administration of the United States government or indicated tests  
21 for a food and drug administration approved drug;

22 (2) centers for medicare and medicaid services national coverage  
23 determinations and medicare administrative contractor local coverage  
24 determinations; or

25 (3) nationally recognized clinical practice guidelines and consensus  
26 statements.

27 (ii) Risk-bearing entities contracted to the medicaid program to  
28 deliver services to recipients shall provide biomarker testing at the  
29 same scope, duration and frequency as the medicaid program otherwise  
30 provides to enrollees.

31 (iii) The recipient and participating provider shall have access to a  
32 clear, readily accessible, and convenient process to request an excep-  
33 tion to a coverage policy of the medicaid program or by risk-bearing  
34 entities contracted to the medicaid program. Such process shall be made  
35 readily accessible to all participating providers and enrollees online.

36 (iv) As used in this paragraph, the following terms shall have the  
37 following meanings:

38 (1) "Biomarker" means a characteristic that is objectively measured  
39 and evaluated as an indicator of normal biological processes, pathogenic  
40 processes, or pharmacologic responses to a specific therapeutic inter-  
41 vention. Biomarkers include but are not limited to gene mutations or  
42 protein expression.

43 (2) "Biomarker testing" means the analysis of a patient's tissue,  
44 blood, or other biospecimen for the presence of a biomarker. Biomarker  
45 testing includes but is not limited to single-analyte tests, multi-plex  
46 panel tests, and whole genome sequencing.

47 (3) "Consensus statements" means statements developed by an independ-  
48 ent, multidisciplinary panel of experts utilizing a transparent method-  
49 ology and reporting structure and with a conflict of interest policy.  
50 Such statements are aimed at specific clinical circumstances and base  
51 the statements on the best available evidence for the purpose of opti-  
52 mizing the outcomes of clinical care.

53 (4) "Nationally recognized clinical practice guidelines" means  
54 evidence-based clinical practice guidelines developed by independent  
55 organizations or medical professional societies utilizing a transparent  
56 methodology and reporting structure and with a conflict of interest

1 policy. Clinical practice guidelines establish standards of care  
2 informed by a systematic review of evidence and an assessment of the  
3 benefits and costs of alternative care options and include recommenda-  
4 tions intended to optimize patient care.

5 § 5. This act shall take effect January 1, 2023 and shall apply to all  
6 policies and contracts issued, renewed, modified, altered or amended on  
7 or after such date.